

REMARKS

The Applicants appreciate the Examiner's thorough examination of the subject application and the indication that claim 5 would be in a condition for allowance if rewritten in independent format. Applicants request reconsideration of the subject application based on the following remarks.

Claims 4-9 are currently pending in the application. Claim 9 has been withdrawn from consideration as being drawn to a non-elected species. Applicants request rejoinder and consideration upon allowance of a generic claim encompassing the subject matter of claim 8 and claim 9.

Claims 4, and 6-8 were rejected under 35 U.S.C. §103(a) as being allegedly unpatentable over Horstmann in view of Leonard and Leeper.

The rejection is traversed.

The present invention provides preparations for percutaneous absorption comprising a mixture of menthol and hexylene glycol. The compositions of the instant invention offer superior physical properties (including cohesive force, finger tack, and bleed), reduced skin irritation, and increased skin permeation compared to compositions having menthol or hexylene glycol but not both. See, for example the data of Table 1 and 2 on pages 27 and 28 of the instant specification.

Thus, Applicants have surprisingly discovered that styrene-isoprene-styrene block copolymer and/or polyisobutylene adhesives comprising both menthol and hexylene glycol offer unexpected and superior properties as a base for preparations for percutaneous absorption.

None of the documents cited in the instant application, taken alone or in combination teach or suggest that preparations comprising both menthol and hexylene glycol would provide any desirable physical properties compared against compositions having only hexylene glycol or only menthol.

As the document is understood, Hortsmann recites, in Example 2, a polyester based composition having a styrene-isoprene-styrene block copolymer resin as a minor component (e.g., about 30% based on polyester and styrene-isoprene-styrene block copolymer content). The Hortsmann composition recited in Example 2 does not include any additional additives.

As the Office Action is understood, the recitation of hexylene glycol as one element in an extensive listing of solubility enhancing additives and skin permeation enhancers. Menthol is not included by Hortsmann in the recitation of suitable solubility enhancing additives and skin permeation enhancers.

However, as the reference is understood, Hortsmann merely recites polyester or polyacrylic compositions which may comprise a styrene-isoprene-styrene block copolymer and may additionally comprise one of several dozen solubility enhancing additives and skin permeation enhancers which may be selected to be hexylene glycol.

Thus, Hortsmann fails to teach the composition provided in claim 4 of the instant invention. Moreover, Hortsmann neither teaches nor suggests that preparations for percutaneous absorption comprising a mixture of menthol and hexylene glycol provide superior physical properties, improved rates of drug delivery and/or reduced skin irritation.

Leonard and Leeper, alone or in combination, fail to overcome the limitations of Hortsmann discussed *supra*.

As the Office Action is understood, Leonard is merely recited for the premise that menthol is a penetration enhancer which can be used with estradiol.

Leeper is merely cited for the purpose of establishing that adding a softener to a rubber is known in the art.

Thus, for at least the reasons discussed herein, the Office Action has failed to establish that claims 4 and 6-8 are *prima facie* obviousness over the cited documents.

As provided in MPEP 2143.01, obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. *In re Fine*, 837 F. 2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F. 2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). As provided above, the references cited, alone or in combination, include no such teaching, suggestion or motivation.

Furthermore, and as provided in MPEP 2143.02, a prior art reference can be combined or modified to reject claims as obvious as long as there is a reasonable expectation of success. *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Additionally, it also has been held that if the proposed modification or combination would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. Further, and as provided in MPEP-2143, the teaching or suggestion to make the claimed combination and the reasonable suggestion of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). As can be seen from the forgoing discussion regarding the disclosures of the cited references, there is no reasonable expectation of success provided in

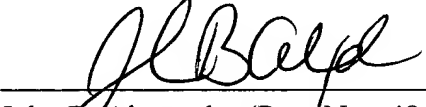
the reference(s). Also, it is clear from the foregoing discussion that the modification suggested by the Examiner would change the principle of operation of the device disclosed in the principal reference.

Reconsideration and allowance of claims 4 and 6-8 is respectfully requested in view of the foregoing discussion. This case is believed to be in condition for immediate allowance. Applicant respectfully requests early consideration and allowance of the subject application.

If for any reason a fee is required, a fee paid is inadequate or credit is owed for any excess fee paid, you are hereby authorized and requested to charge Deposit Account No. **04-1105**.

Respectfully submitted,

August 24, 2004



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